JS 44 (Rev. 11/04)

CIVIL COVER SHEET

APPENDIX H

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS
American Federation of State, County and Municipal Employees, District Council Health and Welfare Fund

(b) County of Residence of First Listed Plaintiff: Phila.
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number): 215-567-3500
William D. Marvin, Esq, Cohen, Placitella & Roth, P.C.
2001 Market Street, Ste. 2900, Phila, PA 19103

DEFENDANTS
Cephalon, Inc.
41 Moores Road
Frazer, PA 19355

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Federal Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury

PERSONAL INJURY
☐ 362 Personal Injury - Med. Malpractice
☐ 365 Personal Injury - Product Liability
☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/ Accommodations
☐ 444 Welfare
☐ 445 Amer. w/Disabilities - Employment
☐ 446 Amer. w/Disabilities - Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence
Habeas Corpus:
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus & Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE/PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R. & Truck
☐ 650 Airline Regs.
☐ 660 Occupational Safety/Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt.Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
☐ 422 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
☐ 820 Copyrights
☐ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 861 HIA (1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW (405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Acts
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Information Act
☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (**Do not cite jurisdictional statutes unless diversity**): 28 USC 1332
Brief description of cause: Refund for improper promotion of prescription drugs.

VII. REQUESTED IN COMPLAINT: ☒ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 **DEMAND $**
CHECK YES only if demanded in complaint: **JURY DEMAND:** ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Petrese B. Tucker DOCKET NUMBER 07-4492

DATE Jan 29, 2009 SIGNATURE OF ATTORNEY OF RECORD [signature]

FOR OFFICE USE ONLY

RECEIPT # ______ AMOUNT ______ APPLYING IFP ______ JUDGE ______ MAG. JUDGE ______

UNITED STATES DISTRICT COURT

APPENDIX F

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: American Fed of State, County and Municipal Employees, 1606 Walnut St. Phila, PA 19103

Address of Defendant: Cephalon, Inc. , 41 Moores Road, Frazer, PA 19355

Place of Accident, Incident or Transaction: Philadelphia, PA

(Use Reverse Side For Additional Space)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?
(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☐

Does this case involve multidistrict litigation possibilities? Yes☐ No☒

RELATED CASE, IF ANY:

Case Number: 07-4492 Judge Petrese B. Tucker Date Terminated: ______

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☒
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☒ No☐
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☒

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases:*
1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases (Please specify)

B. *Diversity Jurisdiction Cases:*
1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☐ Products Liability
8. ☐ Products Liability — Asbestos
9. ☒ All other Diversity Cases (Please specify)

ARBITRATION CERTIFICATION

(Check appropriate Category)

I, William D. Marvin, Esq., counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: Jan 29, 2009 [signature] Attorney-at-Law 34265 Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: Jan 29, 2009 [signature] Attorney-at-Law 34265 Attorney I.D.#

CIV. 609 (4/03)

APPENDIX I

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

American Federation of State, County and Municipal Employees, District Council, 47 Health and Welfare Fund, et al. : CIVIL ACTION

v. :

Cephalon, Inc. :

: NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a case management track designation form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. §2241 through §2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

Jan. 29, 2009	[signature]	William D. Marvin, Esq.
Date	**Attorney-at-law**	**Attorney for** Plaintiff
215-567-3500	215-567-6019	wmarvin@cprlaw.com
Telephone	**FAX Number**	**E-Mail Address**

(Civ. 660) 10/02

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, DISTRICT COUNCIL 47 HEALTH AND WELFARE FUND 1606 Walnut St. Philadelphia, PA 19103 and PHILADELPHIA FIREFIGHTERS UNION LOCAL NO. 22 HEALTH AND WELFARE FUND 415-427 North 5th Street Philadelphia, PA 19123 on behalf of themselves and all others similarly situated Plaintiffs v. CEPHALON, INC. 41 Moores Road Frazer, PA 19355 Defendant	CIVIL ACTION No. 09-

CIVIL ACTION COMPLAINT
Jury Trial Demanded

I. NATURE OF ACTION

1. Plaintiffs bring this action on behalf of themselves and a class of similarly situated entities (the "Class") to recover the hundreds of millions of dollars paid to Defendant as a result of Defendant's unlawful scheme to market and sell the drugs Provigil and Gabitril for unapproved, off-label uses.

2. The FDA has approved Provigil and Gabitril for the treatment of specified sleep disorders and epilepsy, respectively. However, Cephalon implemented an unlawful and deceptive marketing scheme that reached a wide range of doctors, consumers, payors, and others

involved in the selection, approval, distribution, and payment of the costs for prescription drugs, in order to promote usage of these drugs for other indications.

3. Plaintiffs and members of the Class have been injured by the payment of excessive prescription costs for treatment of conditions not approved by the FDA, resulting from the defendants' improper and illegal promotion of such unapproved uses.

II. PARTIES

A. The Proposed Class Representatives

4. Plaintiff American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Fund, is a health and welfare trust fund providing medical benefits, including prescription drug coverage, to members and their dependents, representing active or retired employees of the City of Philadelphia, with offices in Philadelphia at the address above.

5. Plaintiff Philadelphia Firefighters Union Local 22 Health and Welfare Fund, is a health and welfare trust fund providing medical benefits, including prescription drug coverage, to members of the local and their dependents, representing active or retired employees of the Fire Department of the City of Philadelphia, with offices in Philadelphia at the address above.

B. Defendant

6. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business located in Frazer, Pennsylvania. Defendant is in the business of manufacturing, selling and distributing pharmaceutical drugs, with an emphasis on drugs that affect the central nervous system.

7. From prior to January 2001 through the present, defendant Cephalon manufactured, distributed, supplied and sold prescription drugs by the trade names of "Provigil" (chemical name: modafinil) and "Gabitril" (tiagabine HCL) in interstate commerce, throughout the United States.

III. JURISDICTION AND VENUE

8. This Court has personal jurisdiction over the defendant because Cephalon's principal place of business is in this district, and a substantial portion of the events giving rise to these claims took place in this district.

9. This Court has subject-matter jurisdiction over this nationwide class action pursuant to 28 U.S.C. § 1332 as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds $5,000,000, exclusive of interest and costs, and is a class action in which some members of the Class are citizens of states different than Defendant. 28 U.S.C. § 1332(d)(2)(A).

10. This Court also has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, and 18 U.S.C. § 1964(c), because this action alleges violation of the Racketeer Influenced Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(1) and 1391(b)(2) because Defendant resides in and conducts business in this judicial district, and because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in and near this judicial district.

IV. GENERAL ALLEGATIONS

A. Regulatory Framework

12. In the United States, the marketing and sale of prescription drugs is strictly regulated by the U.S. Food and Drug Administration ("FDA"). A manufacturer may distribute a drug only if it is approved by the FDA. 21 U.S.C. § 355(a). In order to secure the FDA's approval, a manufacturer must show that the drug is "safe for use" for "all conditions prescribed, recommended or suggested" on a drug's label. 21 U.S.C. § 355(d). Drug manufacturers, such as Cephalon, are required to demonstrate the safety and effectiveness of drugs for specific intended uses through extensive preclinical studies and clinical trials, a process that typically takes years.

13. The FDA also strictly regulates the labeling of drugs that it approves. Pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C § 301 et seq., and its implementing regulations, 21 C.F.R. § 1.1 et seq., labeling must contain "adequate directions for use." 31 U.S.C. § 352(f). "Adequate directions for use" must include a "[s]tatement of all conditions, purposes, or uses for which such drug is intended." 21 C.F.R. § 201.5. "Intended uses" are determined by reference to the objective intent of the persons legally responsible for the labeling of the drug, and "may be shown by ... advertising matter, or oral or written statements by such persons or their representatives," or by "the circumstance that the [drug] is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." 21 C.F.R. § 201.128. "[I]f a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is put." Id.

14. Labeling must also contain "adequate warnings against use" when taking or administering the drug may be dangerous. 31 U.S.C. § 352(f). "[L]abeling must be revised to

include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." 21 C.F.R. § 201.57(c)(6). In addition, a specific warning relating to a non-approved use may be required "if the drug is commonly prescribed for a disease or condition and such usage is associated with a clinically significant risk or hazard." Id.

15. A drug that fails to comply with the foregoing regulations is deemed misbranded and may not be distributed in interstate commerce. 21 U.S.C. § 331.

16. All advertisements for an FDA-approved prescription drug must present "a true statement in brief summary" relating to the drug's side effects, contraindications and effectiveness. 21 C.F.R. § 202.1(e)(1). Advertisements may not recommend or suggest any unapproved use. 21 C.F.R. § 202.1(e)(4).

17. An advertisement does not satisfy the requirement that it present a true statement of information in brief summary relating to side effects, contraindications, and effectiveness if: (i) it is false or misleading with respect to side effects, contraindications, and effectiveness; or (ii) it fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness; or (iii) it fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement. 21 C.F.R. § 202.1 (e)(5).

18. Pursuant to applicable regulations, an advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, among other reasons, if it: (i) contains a representation or suggestion, not approved or permitted for use in the labeling that a drug is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience; (ii) contains favorable information or opinions about

a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information; or (iii) contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience. 21 C.F.R. § 202.1(e)(6).

19. No advertisement concerning a particular prescription drug may be disseminated without the approval of the FDA if the sponsor has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage. 21 C.F.R. § 202.1(j)(1)(i). Dissemination of an advertisement not in compliance with this requirement is deemed to be an act that causes the drug to be misbranded in violation of the FDCA.

20. Under the Food and Drug Administration Modernization Act of 1997 ("FAME"), if a manufacturer wishes to market or promote an approved drug for additional uses - i.e., uses not listed on the approved label - the manufacturer must resubmit the drug for another series of clinical trials similar to those for the initial approval. 21 U.S.C. § 360aaa(b), (c). Until subsequent approval of the new use has been granted, the unapproved use is considered to be "off-label."

21. "Off-label" refers to the use of an approved drug for any purpose, or in any manner, other than what is described in the drug's labeling. Off-label use includes treating a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population (e.g., treating a child when the drug is approved to treat adults).

22. Although the FDCA allows a manufacturer to disseminate to health care practitioners and third-party payors written information concerning the safety, effectiveness or

benefits of an unapproved use of a drug, 21 U.S.C. § 360aaa(a), the information disseminated must be in the form of an unabridged (i) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug, which was published in a scientific or medical journal, which is about a clinical investigation with respect to the drug, and which would be considered scientifically sound by such experts; or (ii) reference publication that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug. 21 U.S.C. § 360aaa-1(a)(1). In addition, the information disseminated may not be false or misleading or pose a significant risk to the public health. 21 U.S.C. § 360aaa-1(a)(2). Moreover, a manufacturer that disseminates information on unapproved uses to health care practitioners and third-party payors pursuant to these regulations is required to notify the FDA of any additional knowledge the manufacturer obtains on clinical research or other data that relate to the safety or effectiveness of the new use involved. 21 U.S.C. § 360aaa-4(a)(2) . The FDCA prohibits the dissemination of information concerning unapproved uses in violation of these provisions. 21 U.S.C. § 331(z).

B. Cephalon Internationally Circumvented the FDA's Off-Label Approval Process and Engaged in Off-Label Marketing Efforts to Expand the Use of Provigil and Gabatril

23. In 1998, the FDA approved Provigil to treat excessive daytime sleepiness associated with narcolepsy. In 2004, the FDA approved the expansion of Provigil's label to include the treatment of excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.

24. From approximately January 2001 through at least 2006, defendant Cephalon improperly promoted Provigil as a non-stimulant drug for the treatment of sleepiness, tiredness, decreased activity, lack of energy and fatigue. These additional intended uses were not approved

by the FDA. In promoting Provigil for these new intended uses, Cephalon caused the drug to be misbranded under 21 U.S.C. § 352(0(1).

25. In 1997, the FDA approved Gabitril as an anti-epilepsy drug indicated as adjunctive therapy in adults and children 12 years and older in the treatment of partial seizures.

26. Beginning approximately January 2001, defendant Cephalon improperly promoted Gabitril to treat anxiety, insomnia, and pain. These additional intended uses were not approved by the FDA. In promoting Gabitril for these new intended uses, Cephalon caused the drug to be misbranded under 21 U.S.C. § 352(0(1).

27. Cephalon knew that Provigil and Gabatril's market potential for its approved uses was quite modest.

28. Cephalon has promoted the off-label uses of Provigil and Gabitril by providing financial incentives to physicians that constitute kickbacks for prescribing and speaking on behalf of non-approved uses of Provigil and Gabitril. Cephalon has also provided benefits to other high-prescribing physicians who attend meetings at attractive locations to induce them to prescribe Provigil and Gabitril for off-label purposes.

29. By these and other means, described in more detail below, Cephalon has misrepresented the safety and efficacy of the off-label uses of Provigil and Gabitril.

30. Cephalon's wrongful conduct has been ongoing from at least 2001 and, on information and belief, likely for years before that. Cephalon's wrongful conduct continues through the present.

31. Despite the limited indications for approved uses of Provigil and Gabitril, Cephalon has put inordinate emphasis on their sales. During 2001-2002, Cephalon more than doubled its sales force. 2002 Cephalon Annual Report at 5.

32. Further, Cephalon has stated that "In 2003, we expect to triple our marketing and medical education expenditures to reach out to additional physicians." *Id.* at 11. Cephalon listed 760 physicians as members of its Speakers Bureau. The focus on pushing its products paid off: That 2002 Annual Report stated that Gabitril sales increased 98% and Provigil sales increased 31%. *Id.* at 11.

33. Cephalon's emphasis on sales is an emphasis on off-label sales. The FDA has only approved Gabitril for epilepsy, but most of its use (reportedly 88%) is for off-label treatment of depression, anxiety, Tourette's Syndrome, chronic pain and other non-seizure conditions. Indeed, a high-prescribing doctor, who is the beneficiary of Cephalon's kickbacks, indicates that of the 400 patients in his practice for whom he has prescribed Gabitril, "none of them" suffer from epilepsy. In other words, all his Gabitril prescriptions are off-label.

34. Cephalon's Provigil has only been approved for specific sleep disorders, notably narcolepsy, which is an "orphan" disease affecting 140,000 Americans. Yet, in 2002, Cephalon reported $200 million in Provigil sales or nearly half of the company's total revenues. A significant majority (reportedly 80%) of the Provigil sales were off-label.

35. Off-label uses of Provigil have included treatments for adults for chronic fatigue, depression, multiple-sclerosis, Parkinson's disease, anxiety, neuropathic pain and spasticity. The most dangerous off-label use is the treatment of Attention Deficit-Hyperactivity Disorder ("ADHD") in children.

36. Absolutely no FDA approval exists for any of these off-label uses and only a few studies have even considered Provigil for pediatric application.

37. At least one such study is very suspect because the "research" was performed by a high-prescribing and well-compensated Cephalon speaker named Dr. Thomas A. Rugino. More

importantly, the study investigated the use of Provigil on only a minuscule group of fifteen children, four of whom were excluded from the final study group. One of the four excluded children developed disorientation and severe tremors and had to be removed from the group.

38. When discussing this study, Cephalon speakers make no mention of this child's reaction to Provigil. Cephalon's conduct is thus false by omission.

39. By the paucity of supporting studies and the omitting of negative information from lectures, Cephalon has placed in jeopardy infant children patients who are being given Provigil by prescriptions written by doctors induced by Cephalon's off-label promotion.

40. Cephalon aggressively sells Provigil as an ADHD treatment drug to make large sums of money and expand the market for the company. Indeed, Cephalon has an entire Provigil program devoted to ADHD treatment. That program is completely off-label.

41. In sum, Cephalon's focused, high-volume, off-label promotion is pernicious to the statutory/regulatory scheme and dangerous to the pediatric patients who receive the drug.

42. Cephalon is no stranger to unlawful off-label marketing that attempts to evade FDA approval procedures. On January 3, 2002, the FDA in a letter to Cephalon's Paul M. Kirsch, Senior Director of Regulatory Affairs, sharply reprimanded Cephalon for its "dissemination of false or misleading [Provigil] promotional materials" in violation of the Food, Drug and Cosmetics Act and applicable regulations. The FDA had reviewed Provigil's promotional materials (sales advertisements, journal advertisements and public website). The FDA disciplined Cephalon for suggesting in those materials that Provigil was safe and effective for a variety of unapproved uses "such as fatigue, tiredness and lack of energy". Indeed, the FDA attached 72 pages of Cephalon promotional materials to its letter, and the FDA was highly

critical of much of this material. The FDA found Cephalon guilty in that it made "misleading" claims "for unapproved uses."

43. In an apparent response to the FDA's reprimand, Cephalon removed that off-label information from its public website. Cephalon, however, has continued to flout the ruling of the FDA by touting physicians to promote off-label uses of Provigil and Gabitril on its password-protected website. On information and belief, Cephalon provides targeted, high-prescribing physicians with passwords to access that off-labeling information on its website. In other words, the goal of off-label promotion is the same. Cephalon has simply re-directed its strategy to keep it away from the FDA's regulatory oversight.

44. In January 2002, shortly after defendant CEPHALON embarked on its off-label campaign promoting Provigil for wakefulness, the FDA sent CEPHALON a letter requiring the company to cease disseminating false and misleading written promotional materials representing that Provigil was better, safer, more effective, or useful in a broader range of conditions or patients than the FDA had approved. CEPHALON's written promotional materials included assertions that Provigil was useful for sleepiness, tiredness, decreased activity, lack of energy, and fatigue.

45. In February 2005, once the FDA learned about seizures in some patients who had been prescribed Gabitril for conditions other than epilepsy, the agency issued a public health advisory. The FDA also required defendant CEPHALON to add a bolded warning on the Gabitril label advising doctors of the association between Gabitril and seizures in non-epileptic patients, and to send a letter to doctors advising them of the Gabitril-seizure association.

46. Defendant has improperly promoted the medically unnecessary use of Cephalon drugs, which resulted in improper billings to Plaintiffs and Class Members.

C. Kickbacks

47. Cephalon has provided monetary incentives to doctors who are high-prescribers of Provigil and Gabitril by paying lucrative fees to them for speaking at lectures, dinner meetings and teleconferences. One such high-prescribing physician and prolific Cephalon speaker stated that Cephalon pays him $1,500 per lecture, more than other drug companies. He estimated that he speaks 3 to 4 nights per week and does "a lot for Cephalon."

48. The lucrative speaking fees are remuneration for past high-prescribing and inducements to write future prescriptions for off-label use of Cephalon products. In the words of the same physician, "If you don't pump the numbers, then [the drug companies like Cephalon] are not gonna be that interested in [you]. . . . I'm a high prescriber and I give a good lecture." (This is the same physician with 400 patients on Gabitril, none with the FDA approved indication of epilepsy.) The benefits are also inducements to influence the high-prescribing speakers to tout the off-label uses of Cephalon products to audiences of influential physicians.

49. Cephalon targets such influential doctors to be attendees of lectures. The lectures typically take place at attractive locations. One such weekend event on June 21-23, 2002, was at the Four Seasons Aviara, "a deluxe resort" near San Diego. Cephalon paid for the travel, hotel and meal expenses of the attendees. Cephalon also paid for leisure activities such as golf, tennis lessons, sightseeing, spa treatments and deep sea fishing. As the San Diego "Provigil Consultants Meeting" suggests, these events are in reality little more than paid vacations for high-prescribing physicians to speak on or to receive Cephalon's promotional messages regarding the off-label uses of Provigil and Gabitril.

50. To the same end, Cephalon also holds smaller programs involving dinners at high-end restaurants. Similarly, Cephalon organizes teleconferences where invitees may be paid, purportedly, for their time.

51. Cephalon is engaging in direct marketing often under the guise of presenting legitimate, independent CME programs. Dates, times, faculty and locations are all suggested by Cephalon. Cephalon participates in the audience selection to get 70-80% of its target group. Cephalon representatives help deliver invitations. Cephalon slides are used. The Cephalon speakers invariably move into telling how they really use Provigil and Gabitril— off-label. That is the purpose of the lectures, dinners and teleconferences.

52. Kickbacks have the effect of reducing a patient's healthcare choices as unscrupulous physicians steer the patient to off-label products based on the physician's own financial interests, rather than the patient's medical needs. More basically, kickbacks undermine the physician's medical judgment as to the appropriate drug to prescribe.

53. Cephalon conducted off-label marketing on its public website (along with off-label advertising in periodicals). Cephalon apparently shifted strategy after being reprimanded by the FDA in January 2002. Now Cephalon has posted on its password-protected website off-label information available to targeted physicians. Cephalon has provided its speakers with materials promoting the off-label uses of Provigil and Gabitril for the purpose of market expansion.

54. That off-label information is false or misleading regarding the safety and efficacy of Provigil and Gabitril. At its lectures, dinners and teleconferences, Cephalon has incompletely described the potential adverse effects of those drugs when used off-label.

55. For instance, Provigil speakers on the off-label uses for ADHD employ professional slide presentations designed and prepared by Cephalon. The slides note some side effects but falsely omit that use could result in dizziness, depression and tremors along with other

conditions. Provigil speakers also falsely omit from lectures the disorientation and severe tremors suffered by one child in a small Provigil study. See ¶ 37, supra.

56. Regarding the efficacy of Provigil for the off-label treatment of ADHD, one Cephalon speaker has privately acknowledged that Provigil would "never be a first line drug" for ADHD. Because of the powerful incentives provided by Cephalon's illegal remuneration, that speaker does not impart his view of Provigil's limited effectiveness to the audiences at lectures funded by Cephalon. Cephalon's illegal largesse undermines the independence and accuracy of the information being provided to its hand-picked audience.

57. The Cephalon-compensated speakers direct their off-label messages at the targeted audience of high-prescribing and influential physicians, who are induced by expense-paid weekends, dinners at high-end restaurants and purported reimbursement for time spent on teleconferences. Cephalon intends that those audiences be made receptive to the Cephalon message that Provigil and Gabitril can and should be used off-label.

D. In-Person Off-Label Promotion Through Sales Representatives

58. Defendant instructed and trained its expanded sales force to promote off-label usage of Provigil and Gabitril.

59. Cephalon directly manipulated its bonus incentive program to encourage promotion of off-label sales.

60. In or about 2000, Cephalon changed its incentive programs, which had been designed to discourage off-label usage. Required sales quotas were substantially increased, and caps were removed from potential bonuses from increased sales beyond quota levels, all in an effort to encourage greater off-label marketing by Cephalon's sales representatives. In fact, required sales quotas came to be raised so high that the only realistic way for sales representatives to reach required quotas was to find ways to increase off-label sales.

61. During this same period, oral presentations from upper management to sales representatives and managers at Cephalon's national and regional sales meetings became more directed to techniques for sales representatives to discuss to potential off-label uses of Cephalon's drugs with physicians without being too obvious.

62. Sales representatives who balked at participating in the off-label marketing of Provigil and other Cephalon drugs through bogus "Medical Education Programs" were rebuked and financially punished by the company. For instance, one whistleblower sales representatives was denied the bonus he had otherwise earned through his direct sales efforts in 2002 because he recognized such Medical Education Programs as improper off-label marketing and thus refused to utilize that marketing device as a means of keeping pace with other sales representatives who were willing to do as the company expected.

63. One sales representative that filed a *qui tam* action expressed her concern to her direct supervisor that his direction to focus solely on psychiatrists for the marketing of Gabitril, even though psychiatrists had no known use for the FDA-approved purpose of Gabitril, was repeatedly criticized in her written Performance Appraisals beginning in 2001. She was criticized for not being aggressive enough in "identifying and developing new accounts in psychiatry," for not embracing the "GABA mechanism of action story," and not being "persuasive" enough in off-label marketing. She was also criticized for not instructing psychiatrists that the maximum dosage for various off-label uses of Gabitril was 32-56 milligrams, even though the FDA has not provided any dosage requirements for such purposes. Ultimately, she was terminated.

64. This same sales representative was instructed to write her field notes in such a way so as to disguise her off-label marketing efforts. Numerous Cephalon district managers

instructed their sales representatives to simply write the notation "product reminder" in their field notes so not to create evidence of off-label marketing.

65. At the same time Cephalon was pressuring its existing sales force to market off-label so that the company could make its sales growth goals, it also developed hiring criteria for potential new sales representatives that inquired whether the candidate would be able to "work within the gray area" of off-labeling marketing.

66. To encourage off-label promotion of Provigil by its sales force, Cephalon de-emphasized sales calls to sleep specialists, who were likely to be treating patients with approved, on-label indications for use of Provigil, and directed its sales representatives instead to concentrate their sales calls increasingly on psychiatrists whom Cephalon's research indicated were treating patients likely to suffer the kinds of disorders for which off-label prescriptions could be solicited. Such targeting was done, for example, with psychiatrists who prescribed substantial amounts of anti-depressant drugs, as a means of attempting to develop off-label sales of Provigil for fatigue associated with depression. Cephalon told its sales representatives that they should plan on visiting target physicians 8-10 times per year in order to achieve increased productivity of those physicians in writing new prescriptions for Cephalon drugs.

67. With respect to Gabitril, sales representatives were given visual aids demonstrating the so-called "science" of Gabitril, i.e., the manner in which Gabitril functioned to control partial seizures related to epilepsy (its FDA approved use), by enhancing the activity of GABA, the major inhibitory neurotransmitter.

68. The sales representatives were trained and instructed to use the visual aids to discuss the "science" of Gabitril with the psychiatrists in order to explain how Gabitril could be used to treat anxiety, mood disorder, and pain.

69. The visual aids that sales representatives were instructed to use with psychiatrists make no reference to pain, mood disorder, or anxiety. Cephalon reasoned that because GABA directly affects anxiety, mood disorder, and pain, and, because Gabitril impacted upon GABA, Gabitril should be effective in treating all these illnesses.

70. However, as Cephalon knew, the FDA has not approved Gabitril for any of these purposes, and there were no FDA approved studies on Gabitril to determine its efficacy in the treatment of anxiety, mood disorder, or pain.

71. The sales representatives had no legal or scientific basis to promote Gabitril in such discussions with physicians. Even if Gabitril were being actively tested for such purposes, the sales representatives would not be authorized by the FDA to promote Gabitril for such purposes. Moreover, the sales representatives were not even remotely qualified or trained to persuade physicians that Gabitril may be effective in the treatment of anxiety, mood disorder, or pain. In fact, Cephalon sales representatives had no reason to call upon psychiatrists to market Gabitril since psychiatrists were not using either medication for a FDA approved purpose.

72. However, Cephalon management instructed sales representatives, that their time and money should be spent in marketing Gabitril off-label to psychiatrists, rather than specialists in seizure disorders, and trained them in seminars and written materials in making presentations to promote off-label prescriptions.

E. Effects of Cephalon's Improper Off-Label Promotion

73. Physicians are free to exercise their independent, informed judgment in the implementation of drug therapy for uses not approved by the FDA. Physicians rely on information supplied by a drug's manufacturer in deciding whether an unapproved use of a drug is appropriate. If information provided by a drug's manufacturer is false or misleading, a

physician cannot accurately assess the crucial risk-benefit balance for the patient or exercise independent professional judgment.

74. Concealment of important information by a drug manufacturer, or providing inaccurate, biased information misleads physician their patients.

75. Cephalon's campaign to mislead and deceive American doctors, third party payors including the plaintiffs, their agents who administer prescription benefit programs, and patients, deprived patients and their doctors of the information necessary to evaluate the risks and benefits associated with prescribing Provigil and Gabatril for off-label usages..

76. At all times, Cephalon knew and intended that its improper and illegal campaigns to promote off-label prescriptions for Provigil and Gabitril would influence and distort the judgment of physicians, and cause them to prescribe these drugs for non-approved, off-label uses, when those physician otherwise would not have prescribed Cephalon's drugs.

77. At all times, Cephalon knew and intended that their misleading and deceptive promotion would influence the medical community generally, and thereby increase acceptance of these off-label usages by all those involved in the distribution of the prescription drugs, including patients, physicians, prescription benefit managers, and payors such as plaintiffs.

78. The ultimate intended target of Cephalon's campaigns was the class of plaintiffs herein, who pay for the cost of the prescriptions for their members and beneficiaries. Cephalon designed and implemented its wrongful campaigns in order to obtain greater sales and profits than it could achieve by limiting its promotion to approved uses.

79. Cephalon thus intended to, and did, cause plaintiffs to spend greater amounts for off-label prescriptions of Provigil and Gabitril, than they would have, if Cephalon had confined its promotional efforts to approved usages..

80. Plaintiffs have expended substantial sums for the purchase of Provigil and Gabitril, that had been prescribed for their beneficiaries for off-label uses, where such prescriptions and the purchase costs were caused by the defendant's illegal and improper promotion, as set forth above. The Plaintiffs were thereby injured as a result of the unlawful conduct alleged herein.

F. Government Investigations and Guilty Plea

81. The U.S. Attorney's Office in Philadelphia, Pennsylvania, investigated Cephalon's marketing practices, which resulted in a settlement agreement at the end of 2007. The investigation involved Cephalon's promotion of Actiq, Gabitril and Provigil. Cephalon has agreed to plead guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act and to pay over $400 million to settle Federal and related state Medicaid claims. This settlement does not provide any relief, however, for private payors such as plaintiffs.

V. CAUSES OF ACTION

COUNT I
VIOLATION OF 18 U.S.C. § 1962(C)

82. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

83. Defendant is a "person" within the meaning of 18 U.S.C. § 1961(3) who conducted the affairs of the Provigil and Gabatril Unlawful Promotion Enterprise (the "Enterprise"), through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

84. The Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Defendant, including its employees and agents, and pain management specialists, CME speakers, paid speakers and doctors paid to publish studies, and the marketing

and publication firms employed by Defendant to promote Provigil and Gabatril for off-label uses. The Enterprise was an ongoing organization that functioned as a continuing unit. The Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. The Defendant is a "person" distinct from the Enterprise.

85. Defendant and the other members of the Enterprise created and maintained systematic links for a common purpose to aid in marketing Provigil and Gabatril for off-label uses. Each of the participants in the Enterprise received substantial revenue from the scheme to promote Provigil and Gabatril off-label use. Such revenue was exponentially greater than it would have been if Provigil and Gabatril was marketed appropriately. All participants were aware of Defendant's control over the activities of the Enterprise with respect to promoting Provigil and Gabatril off-label. Furthermore, each portion of the Enterprise benefited from the existence of other parts.

86. The Enterprise engaged in and affected interstate commerce, because, inter alia, it marketed, sold, or provided Provigil and Gabatril to thousands of individuals and entities throughout the United States.

87. Defendant has exerted control over the Enterprise and has managed the affairs of the Enterprise.

88. Defendant has conducted and participated in the affairs of the Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341 (mail fraud), § 1343 (wire fraud), § 1952 (use of interstate facilities to conduct unlawful activity).

89. Defendant used thousands of mail and interstate wire communications to create and manage its fraudulent scheme. Defendant's scheme involved national marketing and sales

plans and programs, and encompassed physicians, medical marketing firms, and victims across the country.

90. Defendant's use of the mails and wires to perpetrate its fraud involved thousands of communications, including, but not limited to:

a. marketing materials and advertisements about the off-label uses of Provigil and Gabatril for which the drug was not proven to be safe, medically efficacious, and useful, such materials being sent to doctors across the country;

b. communications, including financial payments, with the vendor and physician participants discussing and relating to the publication of articles misrepresenting off-label uses of Provigil and Gabatril;

c. communications with vendor and physician participants that fraudulently misrepresented that Provigil and Gabatril was scientifically proven to be safe, medically efficacious, and useful for off-label purposes;

d. communications with health insurers, payors, prescription benefit managers, and patients, including Plaintiffs, inducing payments for Provigil and Gabatril to be made based on misrepresentations concerning the safety, efficacy, and usefulness of Provigil and Gabatril; and,

e. receiving the proceeds of Defendant's improper scheme.

91. In addition, Defendant's corporate headquarters has communicated by United States mail, telephone, and facsimile with various local district managers, medical liaisons, and pharmaceutical representatives in furtherance of Defendant's scheme.

92. Defendant's pattern of racketeering activity includes acts indictable as mail fraud under 18 U.S.C. § 1341 and wire fraud under 18 U.S.C. § 1343. Defendant's fraudulent scheme

consisted of, inter alia: deliberately misrepresenting the uses for which Provigil and Gabatril was safe and effective so that Plaintiffs and members of the Class paid for this drug to treat symptoms for which it was not scientifically proven to be safe and effective, and actively concealing and causing others to conceal, information about the true safety and efficacy of Provigil and Gabatril to treat conditions for which it had not been approved by the FDA.

93. In implementing its fraudulent scheme, Defendant was acutely aware that Plaintiffs and members of the Class depended on the honesty and integrity of Defendant in representing the medical efficacy of Provigil and Gabatril's uses. It is impractical and unduly expensive for Plaintiffs and the Class to perform their own clinical trials or assemble all known medical evidence relating to Provigil and Gabatril's uses. Plaintiffs also rely on federal law obligating Defendant to provide fair and balanced information about their drug products and reasonably presume that when marketing of Provigil and Gabatril was conducted, it complied with Defendant's obligations under federal law.

94. Defendant's scheme was calculated to ensure that Plaintiffs would pay for Provigil and Gabatril to treat conditions that Defendant knew were not appropriately treated with Provigil and Gabatril.

95. The conduct of the Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Defendant's decision for the Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

96. Defendant's fraudulent marketing scheme depended upon concealing its involvement in off-label promotion of Provigil and Gabatril. Indeed, the Enterprise was created precisely to make it appear to the public that Defendant did not have a hand in any discussions or

promotion of off-label use. Additionally, as described above, Defendant had the Enterprise perform off-label promotion in the semblance of legitimate consultants' meetings, continuing education seminars, journal articles, and medical education events. Also as described above, Defendant's involvement was hidden because Defendant hid its financial connections with the physician participants and used the vendor participants as payment intermediaries. These activities and others described above concealed Defendant's fraudulent promotional activities and Plaintiffs could not have discovered the scheme alleged herein earlier in the exercise of reasonable diligence. Indeed, much of the scheme to this day remains concealed by Defendant.

97. Any applicable statutes of limitations have been tolled by Defendant's knowing and active concealment and denial of the facts alleged herein. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the fraudulent nature of Defendant's conduct. Accordingly, Defendant is estopped from relying on any statute of limitations to defeat any of Plaintiffs' claims.

98. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm Plaintiffs and members of the Class. Each such racketeering activity was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including Plaintiffs and members of the Class. Defendant's racketeering activities are part of their ongoing business and constitute a continuing threat to the property of Plaintiffs and members of the Class.

99. Plaintiffs and members of the Class have been injured in their business and property by reason of these violations in that they have made millions of dollars in payment for Provigil and Gabatril that they would not have made had Defendant not engaged in its pattern of

racketeering activity. By reason of the unlawful acts engaged in by Defendant, Plaintiffs and members of the Class have suffered ascertainable loss and damages.

100. Plaintiffs and members of the Class have sustained injuries that were directly and proximately caused by Defendant's racketeering activity as described above.

101. By virtue of these violations of 18 U.S.C. § 1962(c), Defendant is liable to Plaintiffs and members of the Class for three times the damages they have sustained, plus the cost of this suit, including reasonable attorneys' fees.

COUNT II
VIOLATION OF 18 U.S.C. § 1962(d) BY CONSPIRING TO VIOLATE 18 U.S.C. § 1962(c)

102. The preceding paragraphs are incorporated by reference.

103. Section 1962(d) of RICO provides that it "shall be unlawful for any person to conspire to violate any of the provision of subsection (a), (b), or (c) of this section."

104. Defendant has violated § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Provigil and Gabatril Unlawful Marketing Enterprise, described previously, through a pattern of racketeering activity.

105. Defendant's co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Plaintiffs of money.

106. The nature of the above-described Defendant's co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring

to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

107. As a direct and proximate result of Defendant's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Plaintiffs and members of the Class have been and are continuing to be injured in their business or property as set forth more fully above. By reason of the unlawful acts engaged in by Defendant, Plaintiffs and members of the Class have suffered ascertainable loss and damages.

108. Defendant sought to and has engaged in the commission of and continues to commit overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud violations of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud violations of 18 U.S.C. §§ 1341 and 1346; and,

d. Multiple instances of unlawful activity in violation of 18 U.S.C. § 1952.

109. Defendant's violations of the above federal laws and the effects thereof detailed above are continuing and will continue. Plaintiffs and members of the Class have been injured in their property by reason of these violations in that Plaintiffs and members of the Class have spent millions of dollars for Provigil and Gabatril that they would not have spent had Defendant not conspired to violate 18 U.S.C. § 1962(c).

110. Injuries suffered by Plaintiffs and member of the Class were directly and proximately caused by Defendant's racketeering activity as described above.

111. By virtue of these violations of 18 U.S.C. § 1962(d), Defendant is liable to Plaintiffs and members of the Class for three times the damages Plaintiffs and members of the Class have sustained, plus the cost of this suit, including reasonable attorney's fees.

COUNT III
UNJUST ENRICHMENT

112. The preceding paragraphs are incorporated by reference.

113. Defendant is the manufacturer, seller, and/or supplier of the drugs, Provigil and Gabatril.

114. Defendant, through its wrongful conduct described above, has reaped substantial profits from the sale of Provigil and Gabatril. Defendant's profits would have been reduced, but for its wrongful and unlawful conduct.

115. Accordingly, Defendant has been unjustly enriched by its unlawful and wrongful conduct. Defendant should not be allowed to retain the proceeds from the benefits conferred upon it by Plaintiff and the Class. Defendant knew that Plaintiff and the Class paid or reimbursed for purchases of Provigil and Gabatril that were not medically necessary and were caused by its improper promotion of off-label usage.

116. In equity and good conscience, it would be unjust and inequitable to permit Defendant to enrich itself at Plaintiff's and the Class' expense and retain the benefit of Plaintiff's and the Class' expenditures at the expense of Plaintiff and the Class for Provigil and Gabatril prescriptions for off-label uses. Therefore, Defendant must disgorge its unjustly acquired profits and other monetary benefits resulting from its unlawful conduct and provide restitution and/or rescission to Plaintiff and the Class.

117. Accordingly, Plaintiffs and members of the Class seek full restitution of Defendant's enrichment, benefits and ill-gotten gains acquired as a result of the unlawful and/or wrongful conduct alleged herein.

VI. CLASS ACTION ALLEGATIONS

118. All putative Class members were and are similarly affected by having purchased and reimbursed for Provigil and Gabatril for off-label uses and the relief sought herein is for the benefit of Plaintiff and members of the putative Class. Common questions of law or fact predominate over any questions that may affect only individual members. Questions of law or fact common to the Class include:

a. Whether the defendant violated 18 U.S.C. § 1962(c) by the operation of an Enterprise;

b. Whether defendant engaged in a conspiracy with respect to the Enterprise;

c. Whether Cephalon engaged in marketing practices intended to deceive physician specialties into prescribing Gabitril and Provigil for uses not approved by the FDA;

d. Whether Defendant violated the FDCA by its extensive, sustained promotional campaign;

e. Whether Defendant conspired with pain management specialists, CME speakers, paid doctors, speakers and others to promote Actiq, Gabitril and Provigil for off-label uses;

f. whether Defendant was unjustly enriched as a consequence of its unfair and unjust acts;

g. whether Plaintiffs and members of the Class are entitled to restitution and/or rescission for the costs and expenses in connection with any purchases, reimbursements or other costs related to their purchases and reimbursements of Provigil and Gabatril for off-label uses; and

h. whether Plaintiff and members of the Class are entitled to actual and compensatory damages related to their purchases and reimbursements for purchases of Provigil and Gabatril.

119. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs seek no relief which is antagonistic to the interests of the Class. In addition, Plaintiffs are represented by counsel who are competent and experienced in the prosecution of class actions.

120. A class action is a fair and appropriate method for the adjudication of the controversy, in that it will permit a large number of claims to be resolved in a single forum simultaneously, efficiently, and without the unnecessary hardship that would result from the prosecution of numerous individual actions and the duplication of discovery, effort, expense and burden on the courts that such individual actions would engender. The benefits of proceeding as a class action, including providing a method for obtaining redress for claims that would not be practicable to pursue individually, outweigh any difficulties that might be argued with regard to the management of this class action.

121. Plaintiffs' claims are not only typical of, but also are coextensive with, the claims of the class members. Plaintiffs and all members of the class sustained damages in the same manner as a result of Defendant's wrongful conduct.

122. Plaintiffs have an agreement with undersigned counsel that provides for counsel to advance all reasonable and necessary costs to litigate this action contingent on the success of the action.

123. Plaintiffs and the members of the Class purchased Provigil and Gabatril or reimbursed its Fund members or retirees for their purchases of Provigil and Gabatril.

124. Plaintiffs and the members of the Class have sustained losses and damages including, *inter alia*, paying for supplies of a product which was unmerchantable and has exposed persons whose purchases Plaintiff and members of the Class paid for or reimbursed to unnecessary health risks, including the risk of physical injury and death.

VII. DEMAND FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for:

- an order certifying this matter as a class action with Plaintiffs as Class representatives and designating Plaintiffs' counsel as Class Counsel;
- judgment in favor of Plaintiffs and the Class on each of the foregoing causes of action, in an amount in excess of $75,000 for compensatory and consequential damages for monies paid for off-label use of Provigil and Gabitril, and all other damages and remedies available under the applicable statutes and laws;
- Actual damages, statutory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;
- Pre-judgment and post judgment interest on such monetary relief;
- requiring Defendant to pay the reasonable attorneys' fees and costs of Plaintiff and the Class; and

- such other and further relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Respectfully submitted,

COHEN, PLACITELLA & ROTH, P.C.

By: ______________________
STEWART L. COHEN
WILLIAM D. MARVIN

DATED: Jan. 30, 2009

OF COUNSEL:
BAILEY, PERRIN BAILEY
Fletcher V. Trammell
Texas Bar No. 24042053
440 Louisiana, Suite 2100
Houston, Texas 77002
ftrammell@bpblaw.com
(713) 425-7100
(pro hac admission will be requested)